REMARKS

Claims 3, 4, 14, 15, 18-22, 29, 30, 34, 40, and 51-75 are pending. Claims 3, 34, 40, and 53 are amended. Claim 36 is canceled herein. The amendments to claims 3 and 53 are supported in the specification, for example, at paragraphs [0076] and [0077]. The amendment to claim 34 is supported by previously presented claim 36 and the amendment to claim 40 is supported by original claim 34 and original claim 40.

35 U.S.C. § 112 Rejection

Reconsideration is respectfully requested of the rejection of claim 34 as not satisfying the enablement requirement of 35 U.S.C. § 112. Without conceding the propriety of the rejection and in order to advance prosecution, claim 34 has been amended to require that the animal subject is suffering from renal insufficiency, renal failure, or end stage renal disease (ESRD). Thus, the claim is limited to animals suffering from specific diseases and a skilled person would have been able to test the pharmaceutical compositions for effectiveness against these specific diseases using only routine experimentation. Thus, amended claim 34, and the claims that depend therefrom are enabled under 35 U.S.C. § 112.

35 U.S.C. § 102 Rejection

Reconsideration is respectfully requested of the rejection of claims 3, 4, 14, 15, 18-21, 29, and 51-75 as anticipated by Gardon et al. (U.S. Patent No. 3,874,907) under 35 U.S.C. § 102. Claim 3 is directed to a pharmaceutical composition; this composition comprises a pharmaceutically acceptable excipient and core-shell particles, the core-shell particles having a core component and a shell component. The core component comprises a potassium-binding cation exchange polymer. The shell component comprises a crosslinked polymer that has permeability for potassium ion that is higher than the permeability for a competing cation, is essentially not disintegrated during residence and passage through the gastro-intestinal tract of an animal subject, and has a thickness ranging from about 0.002 microns to about 50 microns.

Gardon et al. disclose microparticles for use in separating urea from saline solutions in artificial dialysis machines or ultrafiltration kidney machines. These microparticles have a core polymer of crosslinked polymer with sulphonic acid groups and a polymer skin coating that contains quaternary ammonium groups.

Gardon et al. do not disclose the pharmaceutical composition of claim 1 which requires a core-shell particle *and* a pharmaceutically acceptable incipient. Gardon et al. merely disclose microparticles that are used ***in kidney or dialysis machines***; they are not administered directly to a patient. Thus, Gardon et al. do not disclose the pharmaceutical composition comprising a pharmaceutically acceptable incipient required by claim 3.

Claim 53 is similar to claim 3, but requires the weight ratio of the shell component polymer to the core component polymer ranges from about 0.0001:1 to about 0.5:1 instead of the shell thickness requirements. Claim 53 is not anticipated by Gardon et al. for the same reasons as claim 3.

In summary, claims 4, 14, 15, 18-21, 29, and 51, 52, and 54-75 depend directly or indirectly from claim 3 or 53, incorporate all the elements of claim 3 or 53, and accordingly, are not anticipated for the same reasons as claim 3 or 53. Therefore, claims 3, 4, 14, 15, 18-21, 29, and 51-75 are not anticipated by Gardon et al. (U.S. Patent No. 3,874,907) under 35 U.S.C. § 102.

35 U.S.C. § 103 Rejection

Reconsideration is respectfully requested of the rejection of claims 30 and 40 as unpatentable over Gardon et al. (U.S. Patent No. 3,874,907) in view of Warchol et al. (U.S. Patent No. 5,413,782) under 35 U.S.C. § 103(a).

Claim 30

Claim 30 depends from claims 3 and 53 and further requires the pharmaceutical composition include an enteric coating. As noted above, Gardon et al. do not disclose pharmaceutical compositions comprising pharmaceutically acceptable excipients. Gardon et al. do not disclose *administering* their microparticles to an animal. They merely use them in kidney or dialysis machines where the use of certain microcapsules to remove "undesirable products,

such as urea."[1] Furthermore, "these microcapsules possess a high urea/salt selectivity, that is to say that they retain urea whilst *being rather impermeable to* ***salt***."[2]

Further, a person of ordinary skill would not have incorporated Gardon et al.'s ex-vivo urea-binding/salt-impermeable microcapsules into a pharmaceutical composition to arrive at the composition of claim 30 just because Warchol used anion exchange resins to deliver theophylline or other therapeutics. It is clear that Gardon et al. intended their microcapsules for ex vivo use and nothing in Gardon et al. or Warchol et al. would suggest a systemic administration.

With respect to the addition of enteric coatings described by Warchol et al. to the Gardon microparticles, the enteric coating was used when sustained release of the therapeutic agent was desired. The enteric coating protects the anion exchange polymer-drug complex from competing anions present particularly in the stomach. These competing anions could compete for the anion binding sites on the anion exchange polymer and prematurely displace the therapeutic drug of the complex.

From the combined disclosure, a person of ordinary skill would not have contemplated that the enteric coating described by Warchol et al. would have been useful for coating the core-shell particles of claim 30. The Warchol et al. disclosure does not support the Office's position that a "skilled artisan would have been motivated to include this enteric coating on the particles of the '907 patent in order to improve the stability of the particles in more acidic environments"[3]. The enteric coating in Warchol was used for preventing competing anions in the stomach and upper gastrointestinal tract from displacing the anionic drug from the anion binding sites of polymer. In contrast, the core-shell particles in the instant claims are therapeutic agents and remove cationic species, particularly potassium, from the gastrointestinal tract. This problem is different from the anionic polymers of Warchol acting as drug delivery agents. The Office's assertion is the product of impermissible hindsight reasoning using applicant's claims as a template. Thus, claim 30 is patentable in view of the cited references under 35 U.S.C. § 103(a).

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[1] Gardon et al. (U.S. Patent No. 3,874,907) at column 2, lines 9-18 and column 14, lines 12-15.

[2] Id. at column 14, lines 16-18, emphasis added.

[3] See Office action dated August 10, 2007 at page 7.

Claim 40

Claim 40 is directed to a method of treating an animal subject suffering from hyperkalemia wherein the treatment comprises administering an effective amount of the pharmaceutical composition of claim 3 or claim 53 to an animal subject in need of such treatment.

The disclosure of Gardon et al. is described above in connection with the § 102 rejections. Gardon et al. fail to disclose methods for treating hyperkalemia by administration of core-shell particles capable of binding potassium.

The Warchol et al. disclosure is described above in connection with claim 30. Warchol et al. fail to describe methods of treatment for hyperkalemia using anion exchange polymers. The anion exchange polymers described by Warchol et al. are merely carriers for various anionic drugs.

The Office has failed to establish *prima facie* obviousness because the combined disclosures would not have led a person of ordinary skill to the invention defined by claim 40 because neither Gardon et al. nor Warchol et al. disclose methods for treating hyperkalemia. It is irrelevant whether the Gardon particles could have been used to bind potassium in some subjects, it would not have been obvious to a person of ordinary skill to use such particles in subjects suffering from hyperkalemia. The combined references contain no disclosure regarding the ability of the particles to bind potassium and a person of ordinary skill would not have known whether the particles would have been useful *in vivo* for such a purpose. Therefore, claim 40 is patentable in view of the cited references.

Provisional Double Patenting Rejection

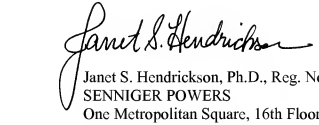
The Office provisionally rejects claims 3, 4, 14, 15, 18-22, 29, 30, 34, 36, 40, and 51-75 on the ground of nonstatutory obvious-type double patenting over claims 1, 10, 16, 17, 20-24, 31, 32, and 45-65 of copending U.S. Serial No. 10/813,872. Without conceding the propriety of this rejection, applicant will consider filing a terminal disclaimer to obviate this basis for rejection when the application is otherwise in condition for allowance.

CONCLUSION

Applicant submits that the present application is now in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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